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I, LEANNE MYNOTT, MANAGER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. 2003906592 for a patent by GEORGE KALADELFOS as filed on 27 November 2003.

WITNESS my hand this
Fourteenth day of December 2004

LEANNE MYNOTT
MANAGER EXAMINATION SUPPORT
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P/00/009
Regulation 3.2

AUSTRALIA

Patents Act 1990

PROVISIONAL SPECIFICATION

Invention Title: **Ligature carrier**

The invention is described in the following statement:

Ligature carrier

Field of the invention

The present invention relates to a surgical device of the type which can be used for inserting sutures within a human or animal body through a confined opening. The invention will be particularly described with reference to a ligature carrier particularly suited for transvaginal sacrospinous colpopexy, but it is to be understood that the device of the invention may be used in other applications.

Background of the invention

Transvaginal colpopexy has become, in recent years, the preferred treatment of vaginal or vault prolapse or vaginal eversion. This condition tends to be caused by failure of the supporting mechanism of the upper genital tract. Treatment of the condition requires the attachment of the vault to a suitable attachment point within the body, the preferred attachment points being the coccygeus muscle-sacrospinal ligament complex located on either side of the patient's pelvis. Attachment of each side of the vault to the left and right sacrospinal ligaments has been performed either abdominally or transvaginally, the latter procedure being preferred for reasons such as patient health and wellbeing.

One problem with performing the procedure transvaginally is that the surgeon is obliged to perform the procedure through the relatively confined vaginal passage. Furthermore, the artificial ligaments need to be attached at some depth within the patient's body, typically the sacrospinal ligaments, which has meant that some form of elongate ligature carrier and suturing device is required to perform the procedure.

Various prior art elongate suturing devices have been developed, but for one or other reason the prior art devices currently available are not ideal for performing the procedure. One reason for this is that the sacrospinal ligaments run transverse to the length of the vaginal passage. It is desirable for the sutures to be placed transverse to the length of the ligaments, not parallel to the length of the ligaments, but prior art devices make it technically difficult to place the sutures in this way.

It is also desirable that, whatever elongate suturing device is used for placing the sutures in the ligaments, the device can effectively perform the procedure on its own, without requiring the assistance of either the surgeon's finger tips, or another instrument used in conjunction with the suturing device. This is due to the fact that the passage through which the surgeon is working is narrow and if another instrument or the surgeon's other hand occupies the passage then placing the suture has to be done 'blind" or by feel, and this makes the procedure far more difficult. If the surgeon is obliged to use two instruments in the suturing procedure then both hands are occupied with suturing, rather than one being free to manipulate or orientate the vaginal passage with retractors.

Various instruments have been developed specifically for performing the procedure. These include the Veronikis device, described in Obstetrics & Gynecology, Vol 89, No 3, March 1997. This device, however, requires the surgeon to use a suture hook to capture the suture once it has passed through the ligament. Another device, the Miya hook, requires the surgeon to use his or her fingers of the free hand to properly place the suture. A Laurus needle driver has been used to perform the procedure (see Obstetrics & Gynecology, Vol 89, No 1, January 1997). This procedure requires both the surgeon to use his or her fingers in the placement, as well as retrieving the needle after it has passed through the ligament. A further device which is used to perform the procedure is the Shutt Suture Punch, but once again, this device requires the suture to be retrieved after it has passed through the ligament.

A further problem encountered when performing the procedure is that the coccygeus muscle-sacrospinal ligament complex tends to lie somewhat flat, and therefore does not present well to the suturing device. This is one reason why, with at least some devices, the surgeon needs to use the finger tips of the free hand to press the ligament into a mounded configuration so that the suturing device can take a firm bite of the ligament. Once again, it would be far preferable if the device could function in such a way that the suture could be placed using the device alone, but yet ensure that the suture is passed through sufficient ligament to properly and safely be used to anchor the vault in place.

Summary of the invention

According to the invention there is provided a ligament carrier and suturing device comprising:

an elongate shaft having a handle means on one end thereof and a needle carrier on the other end thereof;

the needle carrier comprising a rigid arcuate tooth pivotally connected adjacent a proximate end thereof by a pivotal connection to said one end of the shaft and pivotable about an axis which lies transverse to the length of the shaft, the needle carrier adapted to carry on the distal end thereof a needle with a suture attached thereto;

a needle capture device locate on the shaft intermediate the two ends thereof which is adapted to engage with and capture the needle carried by the arcuate tooth; and

operating means coupled to the arcuate tooth and operable to cause the tooth to pivot through its arc so that the needle engages with and is captured by the capture device, the operating means being operable from a location at or adjacent said one end of the shaft.

Preferably the shaft includes a passage in which a connecting rod is located, the connecting rod being coupled to the arcuate tooth. The connection between the connecting rod and the arcuate tooth may comprise a lever mechanism for driving the arcuate tooth through its arc. The arcuate tooth may include a slot into which a pin on the distal end of the connecting rod engages, the slot allowing the tooth to pivot through its arc as the connecting rod is moved longitudinally in use. Optionally the needle carrier may be spring biased into a retracted position.

The needle carrier may have a hollow tip in the distal end thereof, the tip adapted to receive the needle therein. The needle may be of arcuate or straight configuration. The needle preferably has a suture connected thereto in axial alignment therewith, extending rearwardly from the needle, the needle carrier having a slot therein through with the trailing suture passes when the device is in its operative condition.

The needle capture device may comprise an automatically actuating latch mechanism adapted to engage with and capture the needle. The needle may have a notch

or undercut with which the latch device will lock when the needle is engaged with the capture device. Alternatively the needle capture device may comprise a manually operable device, operable from said one end of the shaft, which will capture the needle only when manipulated by the user.

The needle capture device is preferably adapted to disengage from the needle after capture of the needle. Optionally the needle capture device is operable from said one end of the shaft to disengage from the needle.

The operating means may be coupled with said handle means. Said handle means may comprise a lever and a grip, and by moving the lever towards the grip the needle carrier will be caused to move through its arc towards the needle capture device.

These and further features of the invention will be made apparent from the description of a preferred embodiment of the invention, given below by way of example. In the description reference is made to the accompanying drawings, but the specific features shown in the drawings should not be construed as limiting on the invention.

Brief description of the drawings

Figure 1 shows diagrammatically the route which the surgeon will follow for vaginal sacrospinal fixation.

Figure 2 shows the manner of attachment of the vagina to the sacrospinous ligaments.

Figures 3 to 5 show side views of a suturing device and ligament carrier of the invention.

Figures 6 to 8 show enlarged side views of the needle and needle capture devices of the invention.

Detailed description of the embodiments

As mentioned previously, the operation known as sacrospinous vaginal vault suspension requires the surgeon to attached the rear or inner portion of the vaginal vault, typically on opposite sides of the vault, to the two sacrospinal ligaments as indicated in

Figure 1 of the drawings. As shown, an incision 10 is made through the lower rear wall of the vagina 12 in order to obtain access to the sacrospinal ligaments 14 located on opposite sides of the patient. The attachment points are indicated by the letter X on the ligaments. Once sutures have been located in the ligaments 14 these may be used to connect artificial ties or ligaments, in the manner described in patent application PCT/AU00/01298. The artificial ties that are used are typically in a form of an inert mesh material adapted to remain permanently within the body. The manner in which the operation is performed need not be described herein in any further detail. Further information may be obtained by reference to the two Obstetrics & Gynaecology articles referred to in the background section of the specification. The information contained in those two documents are incorporated herein by way of reference. Once the operation has been completed the wall of the vagina will be repaired, with the vagina remaining secured to the sacrospinal ligaments using the artificial ties as indicated in figure 2 of the drawings.

The applicant has found that for the reasons discussed previously inserting the sutures into the sacrospinal ligaments can be difficult resulting in a delay to the completion of the operation or, unless care is taken, inferior attachment to the ligaments. Also, as previously mentioned, it is important that the sutures be placed transverse to the length of the ligaments 14, rather than parallel to the length of the ligament 14 in order to achieve optimal and safe attachment.

The device of the invention and its manner of use is shown in figures 3 to 5 of the drawings. It will be appreciated that the device shown is depicted in somewhat schematic fashion but it will be clear from the drawings how such a device could be used in practice.

As shown, the device 18 comprises an elongate shaft 20 having a handle 22 formed on one end thereof and a C-shaped needle carrier 24 located on the other end 26 thereof. Clearly the end 26 will be inserted into the patient's vagina, through the incision 10, in order to make the attachment X in the ligaments 14. Thus, the length of the shaft 20 will be selected to be able to optimally perform the operation. Where it is desired to use the device in other types of operation, clearly the configuration including the length

of the shaft may vary from that shown herein. It is envisaged that the overall length of the device will be approximately 25 cm although, clearly, different length devices could be utilised.

The needle carrier 24 acts as a tooth or spike to pass through the ligament or other tissue through which it is desired to pass a suture. As shown in the diagrams, the tissue is indicated at numeral 14, that being the sacrospinal ligaments referred to previously.

The needle carrier 24 is pivotally connected through pivot pin 28 to extreme positions being the forward end 26 of the shaft 20. Thus, the needle carrier 24 is able to pivot between the retracted position, shown in figure 3 and the engaged position shown in figure 4.

The handle means 22 is used to move the needle carrier 24 between the two extreme positions. As shown, the handle 22 has a fixed leg 30 and a pivotable leg 32 which can be moved forwards and backwards in the direction of arrow 34. A connecting rod 36 is connected to the movable leg 32 via a pivotal connection 38. The forward end of the rod 36 is connected to the needle carrier 24 via pivot pin 40 which locates in a slot 42 formed in the distal end 44 of the needle carrier 24. Thus, when the rod 36 moves back and forward, the pin 40 carries the needle carrier 24 with it, causing the needle carrier to pivot about a pivot pin 28. The rod thus acts on the needle carrier in the manner of a lever to operate the device.

The needle carrier 24 carries a short stub needle 46 on the distal or forward end thereof, the needle 46 being a close or sliding fit in a tubular end portion 48 of the needle carrier 24. The intention is that the needle 46 will not inadvertently detach from the needle carrier 24 in use, but when gripped it will be relatively easy to detach the needle 46 from the needle carrier 24, in the manner described below.

The needle 46 is coaxially joined to a suture 50 in the manner shown in the drawings, the suture 50 extending rearwardly from the needle 46 and out of the tubular end portion 48 of the needle carrier 24 through a slot 52 in the needle carrier. It is considered advantageous that the suture 50 is coaxially joined to the needle 46 so that if, inadvertently, the needle becomes detached from the needle carrier 24 prior to the

operation being completed, the needle 46 may be withdrawn from the patient by simply pulling on the end 54 of the suture, that is, from outside of the patient.

In order to pass the suture through the ligament 14 the forward end 26 of the device will be passed into the patient, in the manner described above, until such time as the needle 46 is located on the far side of the ligament 14. This is the position shown in figure 3 of the drawings. Thereafter the device may be pulled slightly in order to ensure the needle 46 is at least slightly embedded in the ligament 14. It would be appreciated that during this operation, the surgeon is able to visually inspect the location of the needle 46 since the shaft 20 is relatively slender and will not obscure his or her view. Also, the surgeon does not need to place the fingers of his or her other hand within the patient in order to ensure the location of the needle is correct. As mentioned above, the ability to place the suture using only one hand and having an unimpeded view is considered to be important.

When the proper location of the needle has been determined, the handle 32 may be moved towards the handle 30, thereby pushing the connecting rod 36 forward. This will in turn cause the needle carrier 24 to pivot about pin 28 through the ligament 14 into the position shown in figure 4 of the drawings.

It will be noted that the underside of the shaft has a docking opening or receiving aperture 56 therein into which the needle 46 is driven as the needle carrier 24 rotates into its fully advanced position. The receiving opening 56 has a catch mechanism 58 therein which will engage with a slot 60 in the needle 46 to grip the needle 46 and prevent it from being retracted out of the opening 56 when the needle carrier 24 retracts from its fully advanced position. The catch mechanism will be described in more detail below although it is envisaged that it can be either a spring loaded catch mechanism retractable by means of a lever 62 located towards the rear end of the device and connected to the catch mechanism 58 via a tie rod 64. As shown, a spring 66 is provided for urging the catch mechanism 58 into a position ready to engage the needle 60.

The catch mechanism may operate automatically although it is envisaged that some surgeons may prefer to manually cause engagement in which case a connection mechanism other than a spring loaded latch mechanism will be used to engage the needle

46. Once the needle 46 has been engaged, as indicated in figure 4 of the drawings, the leg 32 of the handle will be moved in a direction away from the leg 30 causing the needle carrier 24 to be retracted from its fully advanced position towards the position shown in figure 5 of the drawings. However, since the needle 46 is now captively held in the opening 56 this movement will cause the needle 46 to be engaged from the end 48 of the needle carrier 24 as shown.

By fully retracting the needle carrier 24 to its fully retracted position the needle carrier will be caused to reverse out of the ligament 14 leaving the suture in position as shown in figure 5 of the drawings. Since the suture is located in the slot 52 in the needle carrier 24, as the needle 46 is withdrawn from the needle carrier the suture will disengage from the needle carrier 24 out of the slot 52.

The device can now be retracted from the patient and by slowly pulling the device whilst the needle 46 is retained in the opening 56 the suture will be pulled through the ligament 14 until the two ends of the suture are located outside of the patient. Once this has been achieved the suture will be severed from the needle 46 and the surgeon can proceed with attaching the artificial ligament to the sacrospinal ligament in the manner disclosed in patent application PCT/AU00/01298. Further description of how the operation is completed need not be discussed herein, but it will be understood that by transferring the needle from the needle carrier 24 to the opening 56 and then retracting the needle carrier 24, a one handed insertion of the suture into the ligament can be achieved.

Furthermore, because of the curved configuration of the needle carrier 24 the needle can be driven in a circular arc, and also the hook shaped nature of the needle carrier 24 ensure that a suitable bite of the ligament 14 can be achieved without the surgeon having to manipulate the ligament with his or her fingers. It is envisaged that the needle carrier will have a radius of curvature of between about 0.5 and 3 cm although a radius of curvature of approximately 1 cm is considered to be the preferred configuration for this type of operation.

Three different engagement arrangements between the needle and the capture device are depicted in figures 6 to 8 of the drawings. Clearly, other arrangements are

possible but what is required is a relatively simple arrangement that reliably captures the needle and does not require excess force for engagement. As shown in figure 6, a spring loaded latch 70 is slidable in a slot 72 which lies parallel to the length of the shaft 20. A compression spring 74 is located around a connecting rod 76 of the latch 70 and the latch 70 will move in the direction of arrow 78 when the needle 46 is moved into the opening 56 in the direction of arrow 80. It will be noted that the latch 70 has a bevelled surface 82 against which the needle 46 will press in order to urge the latch back against the action of the spring 74. Once the needle has been fully inserted into the opening 56 the latch will engage in the annular groove 84 located behind the sharp end or head of the needle 46. The compression spring 74 will then hold the latch 70 in the groove 84 so that when the needle carrier 24 is retracted the needle 46 will remain captured in the opening 56. It will be noted that the needle 46 has a shoulder 86 which will located against the forward end of the needle carrier 24. Also the needle carrier 24 is provided with the slot 32 to allow the suture 50 to connect axially into the rear end of the needle 46.

The device shown in figure 7 of the drawing is similar to that shown in figure 6 except that the latch device 70 is provided with a forward facing lever 90. This lever 90 can only be used to disengage the needle 46 from the opening 56 when the device is removed from the patient, but since this is typically the only time when the needle would be required to be disengaged from the opening 56 this arrangement might be preferred in some instances.

The arrangement shown in figure 8 of the drawings, provides a narrow plate 92 with a aperture 94 therein through which the needle 46 passes as the needle passes into the opening 56. The plate 94 is connection to rod 64 which can either be manually manipulable from the rear end of the device, or may be spring loaded to allow for automatic latching of the needle as it is advanced into its fully advanced position.

Clearly there may be many variations to the above described embodiments without departing from the scope of the invention. Some of the features which are considered to be important are the curved nature of the needle carrier which allows the device to take a "bite" of tissue, such as the ligament described herein, even at relatively remote locations within the body, and even where the tissue to be engaged lies relatively

flat. The manner in which the needle detaches from the needle carrier and the fact that the needle could, if necessary, be retracted from the tissue by pulling on the free end of the suture is also considered advantageous over at least some prior art devices. As mentioned previously, where the device is to be used for suturing different types of operations the overall configuration of the device might need to be quite different from that described herein.

It will be understood that the invention disclosed and defined herein extends to all alternative combinations of two or more of the individual features mentioned or evident from the text or drawings. All of these different combinations constitute various alternative aspects of the invention.

The foregoing describes embodiments of the present invention and modifications, obvious to those skilled in the art can be made thereto, without departing from the scope of the present invention.

Dated this 27th day of November 2003

George Kaladelfos

by its attorneys

Freehills Carter Smith Beadle

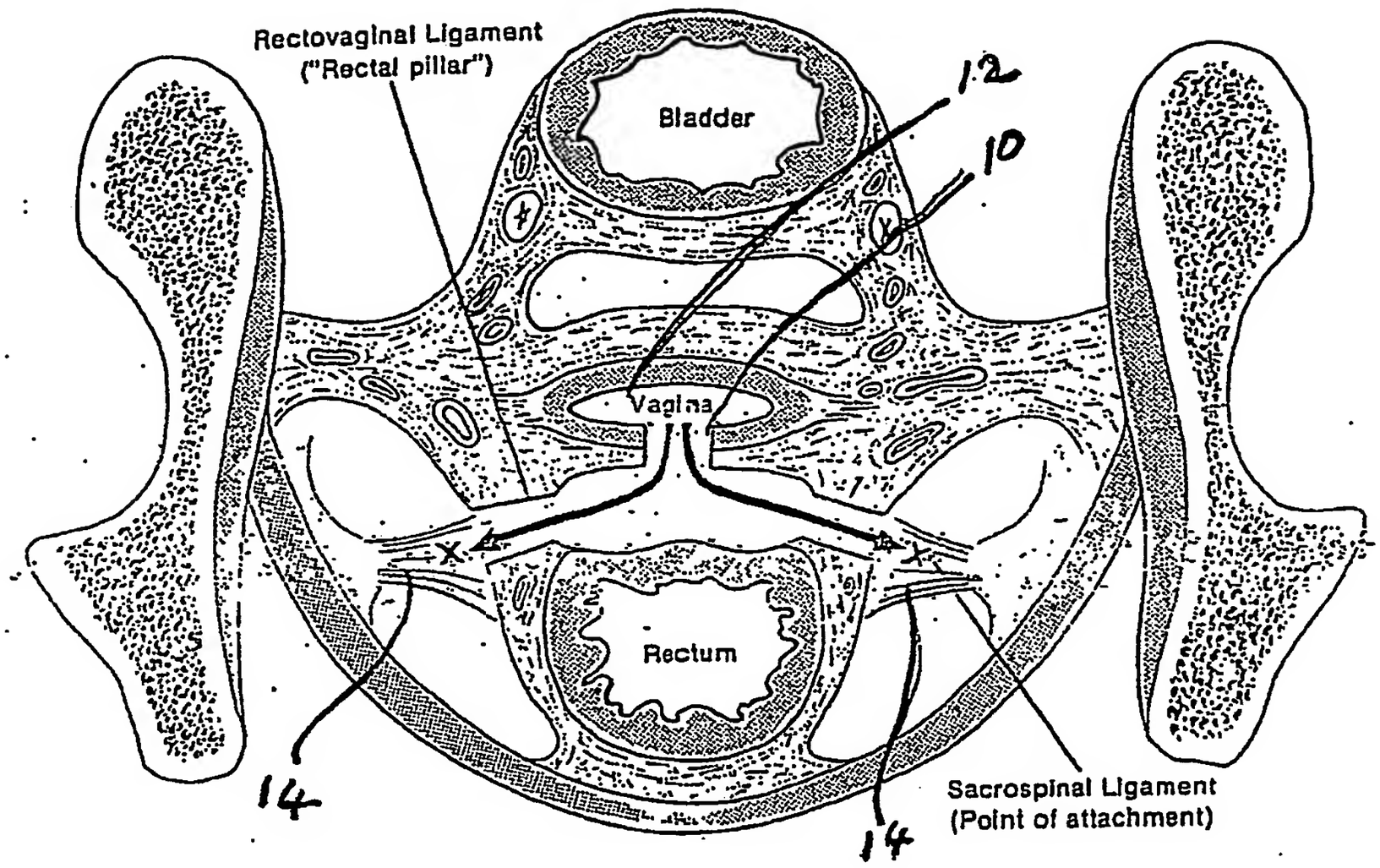
Rectovaginal Ligament
("Rectal pillar")
Bladder
12
10
Vagina
Rectum
14
14
Sacrospinal Ligament
(Point of attachment)

FIG. 1

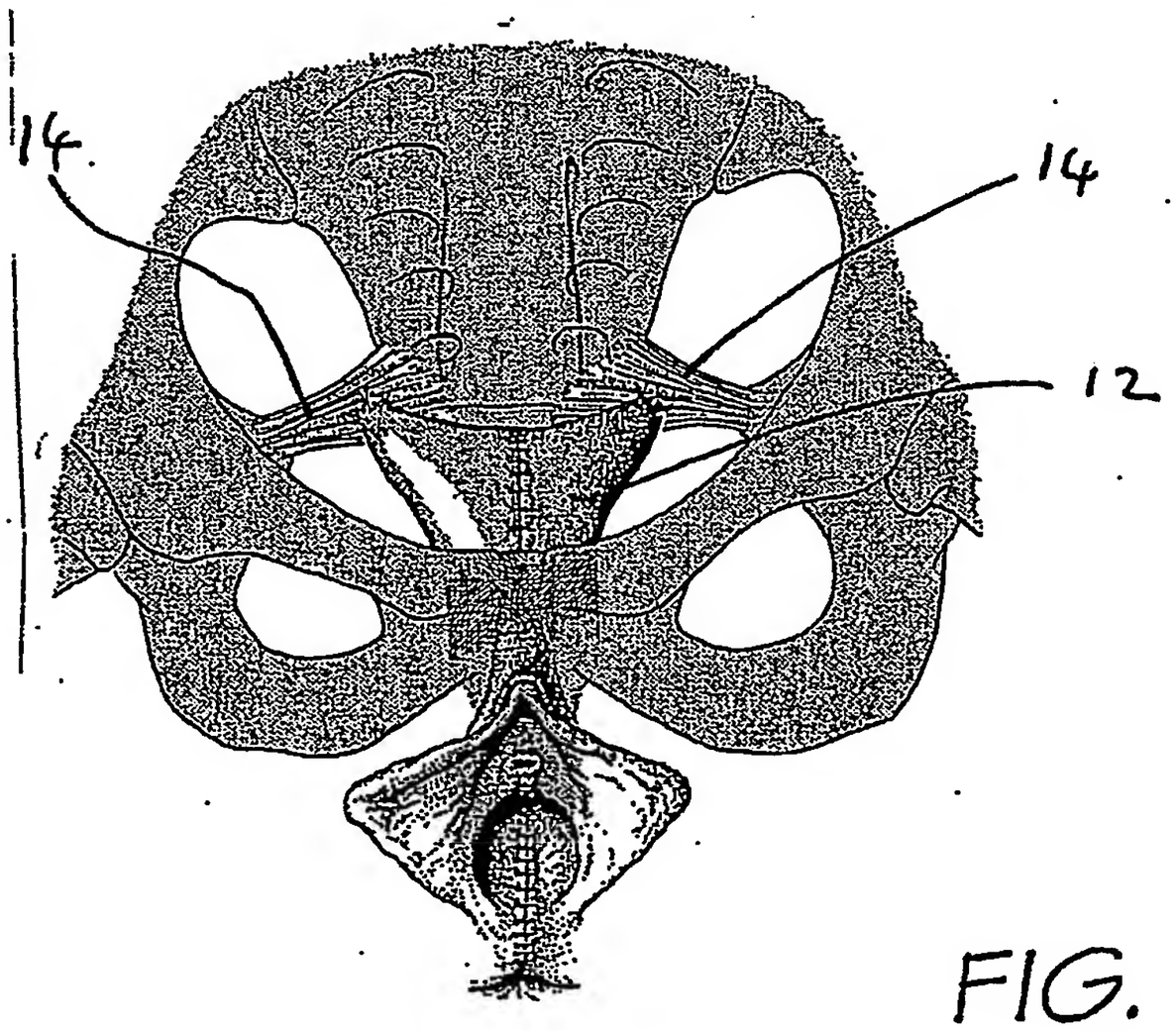
14
14
12

FIG. 2

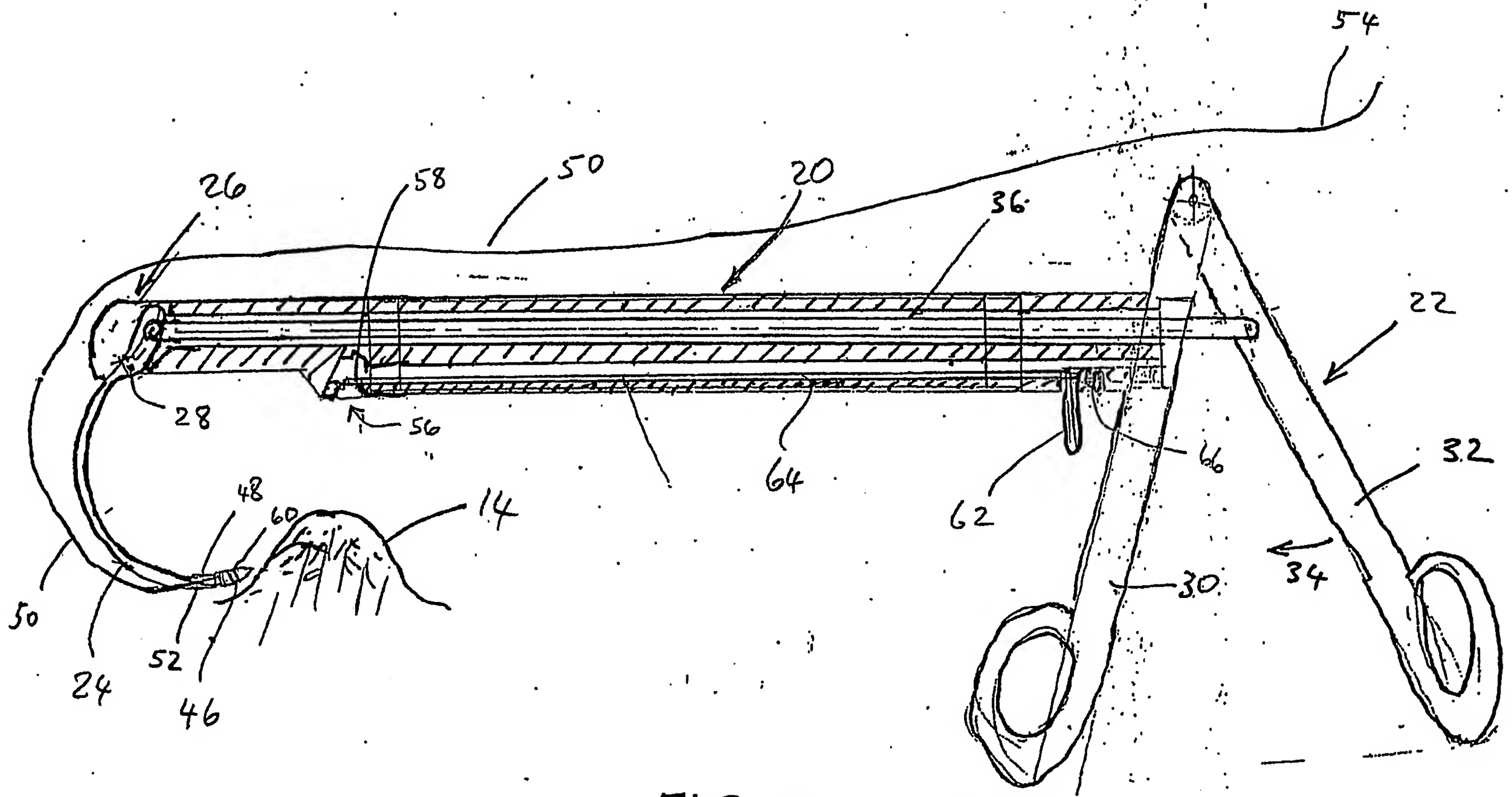

FIG. 3

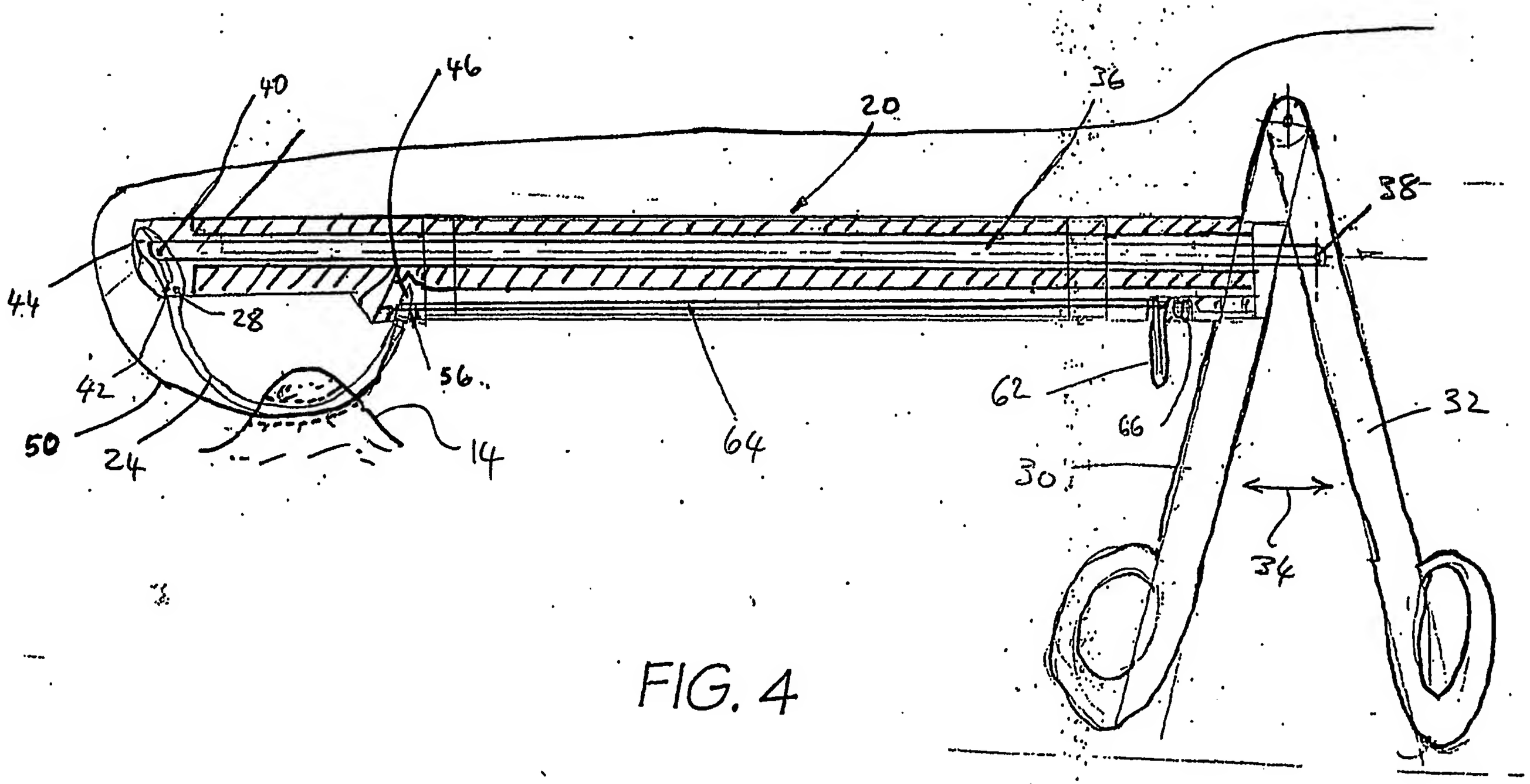

FIG. 4

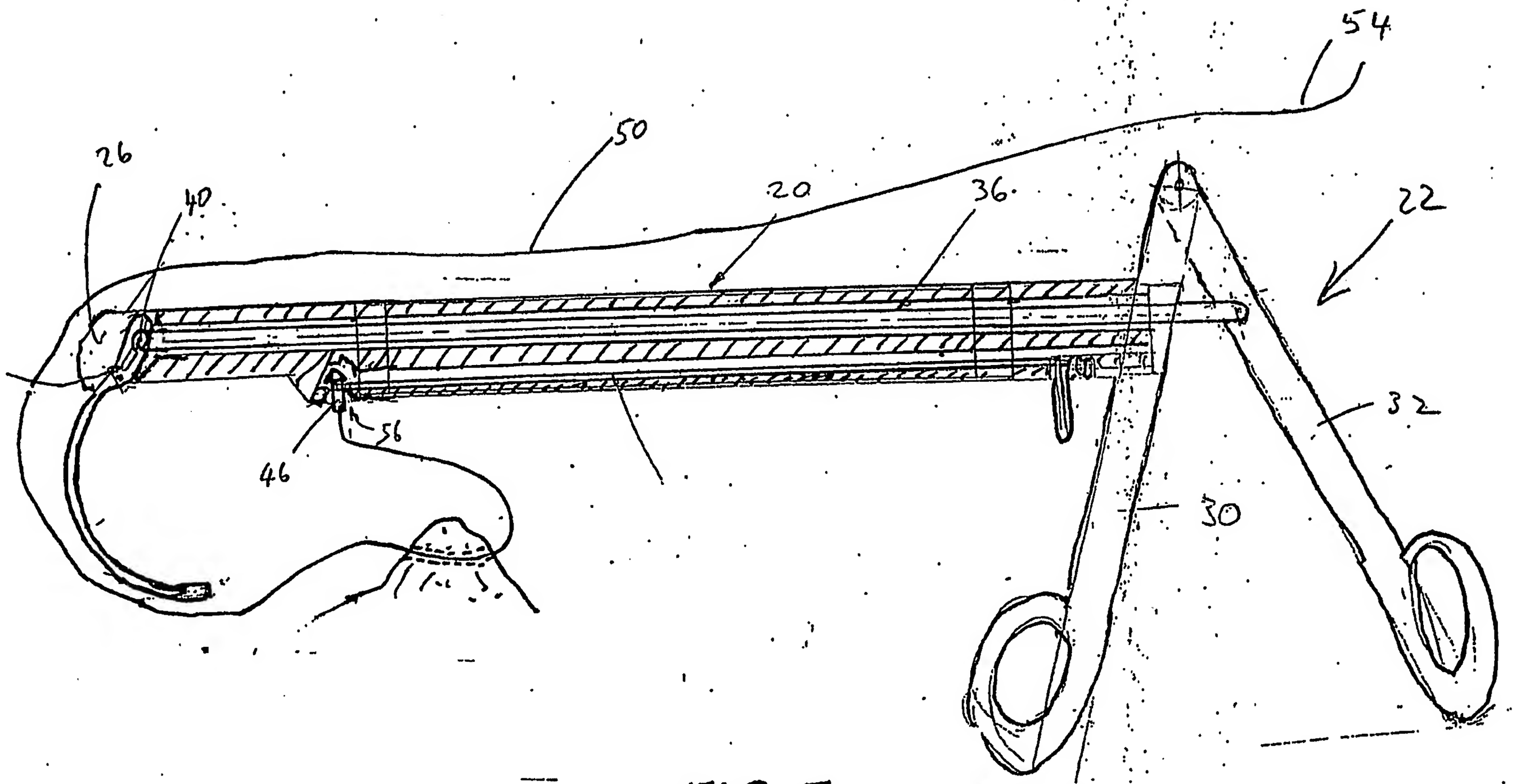

FIG. 5

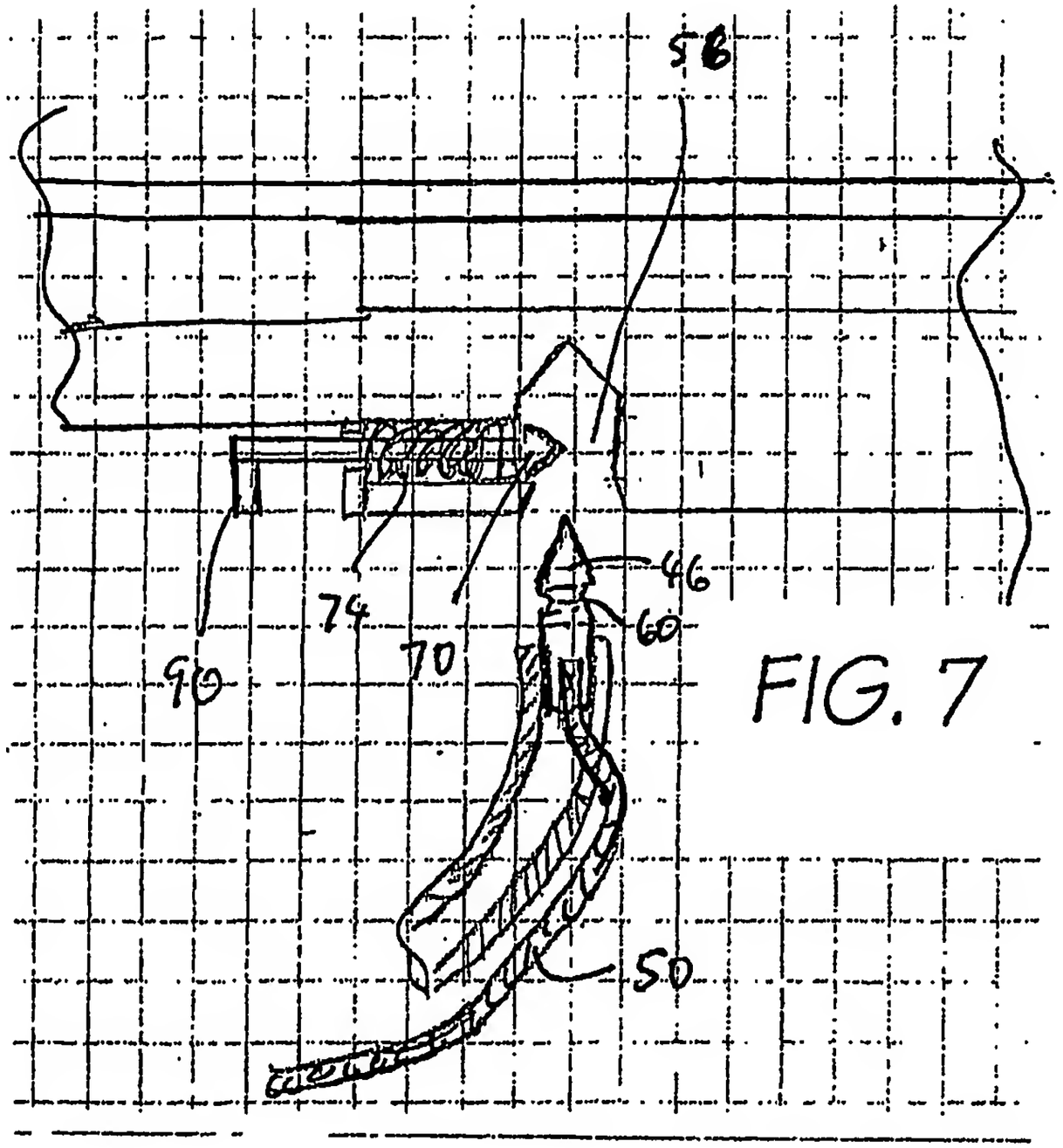

FIG. 7

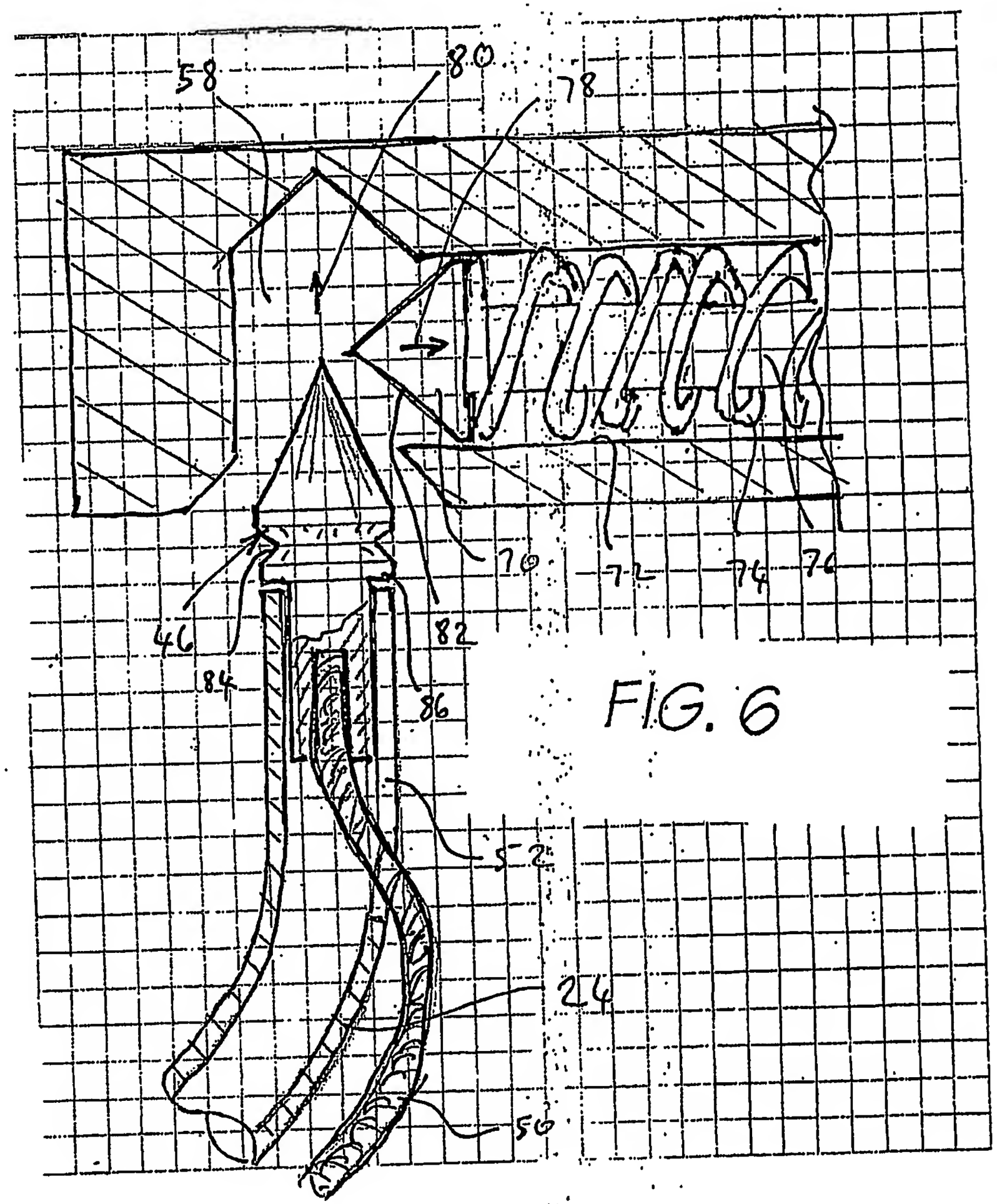

FIG. 6

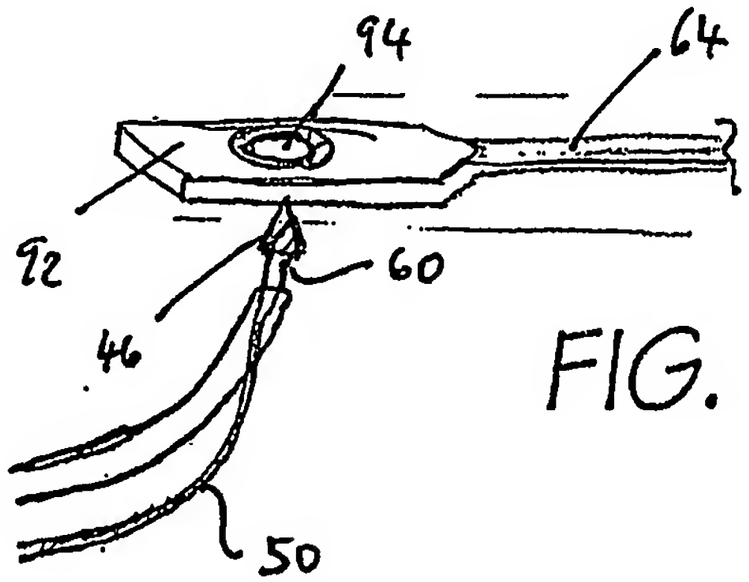

FIG. 8

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